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10/687,566	10/15/2003	Ivan Osorio	011738.00151	7141

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BANNER & WITCOFF, LTD.
TEN SOUTH WACKER DRIVE
SUITE 3000
CHICAGO, IL 60606

EXAMINER	
LE, JOHN H	

ART UNIT	PAPER NUMBER
2863	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,566	OSORIO ET AL.	
	Examiner	Art Unit	
	John H. Le	2863	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,24-31,35,36,42-45 and 50-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9,11-21,26,28,29,31,35 and 42-59* is/are rejected.

7)☒ Claim(s) *5,10,22,24,25,27,30,36 and 60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06/27/03* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Election

1. Applicant's election of Group I (Claims 1-22, 24-31, 35-36, 42-45, 50-53) in Paper No. 6 without traverse is acknowledged. Accordingly, claims 23, 32-34, 37-41, 46-49 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Applicant has the right to file a divisional application covering the subject matter of the non-elected claims 23, 32-34, 37-41, 46-49.

2. Applicant's election and amendment filed 05/23/2005 has been entered and carefully considered.

Claims 1, 4-5, 10-11, 13, 17-22, 25, 35-36, 42-45, 50-53 has been amended.

Claims 54-60 have been added.

Claims 23, 32-34, 37-41, 46-49 have been cancelled.

Drawings

3. The drawings of Figs.1, 2, 4B, 4C, 4D are objected to because lines, numbers, and letters not uniformly thick and well defined, clean, durable, and black (poor line quality). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where

necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because drawings of Figs.1, 2, 3, 4A, 4B, 4C, 4D, 5, 6, 7 because lines, numbers, and letters not uniformly thick and well defined, clean, durable, and black (poor line quality). Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application.

Claim Objections

4. Claim 31 is objected to because of the following informalities:

Claim 31 should be cancelled because it depends on the cancelled claim 23.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4, 12-16, 21, 26, 35, 42, and 45 are rejected under 35 U.S.C. 103(a) as obvious over Aoyama et al. (USP 5,921,938).

Regarding claims 1-4, 21, 26, 35, Aoyama et al. teach a method for synchronizing a plurality of clock, the plurality of clocks comprising a first clock and a second clock (20, 38, Fig.1C), the method comprising:

(a) disabling a run time mode (Fig.2A, step 114);

(b) receiving a selected time associated with the second clock (38), the selected time different than a reference time that is associated with the first clock (20)(e.g. Col.7, lines 1-20), wherein at least one of the first clock or the second clock is associated with a medical device system;

(c) determining when the reference time equals the selected time (Fig.2A, step 118);

(d) setting the second clock to the selected time, in response to (c) (Fig.2B, step 126, time correction); and

(e) enabling the run time mode (Fig.2B, end).

Although Aoyama et al. is silent on the teaching at least one of the first clock or the second clock is associated with a medical device system, however it would have been obvious to one of ordinary skill at the time the invention was

made to teach at least one of the first clock or the second clock is associated with a medical device system since the electronic physiological instrument records medical event data and electronically associates time stamps with the event data (Col.2, lines 21-24).

Regarding claims 42, Aoyama et al. teach a system for synchronizing a plurality of clocks (20, 38) in a medical device system, the medical device system providing treatment to a patient with a nervous system disorder (e.g. Col.1, lines 28-49), the plurality of clocks comprising a first clock and a second clock (20, 38, Fig.1C), the system comprising: a user interface (26); a communications interface (32) that is coupled to the second clock (38); a memory (24); a processor (18) that is connected to the user interface (26) in order to receive an instruction from a user, the processor connected to the memory (24) and the second clock (38) through the communications interface (34, 44), the processor (18) further configured to perform: (a) receiving a selected time associated with the second clock (38), the selected time different than a reference time that is associated with the first clock (20)(e.g. Col.7, lines 1-20); (b) setting the second clock (38) (time correction) to the selected time so as to synchronizine the first (20) and second clock (38)(e.g. Col.7, lines 1-20).

Although Aoyama et al. is silent on the teaching the processor configured to instructs the second clock, however it would have been obvious to one of ordinary skill at the time the invention was made to teach the processor configured to instructs the second clock since the processor (18) connected to

the second clock (38) through the communications interface (34, 44) (Fig.1A, Col.2, lines 21-24).

Regarding claims 12-16, Aoyama et al. teach the selected time is greater than the reference time (Fig.2A, step 118); receiving a command to enable the run mode operation, the command being indicative that the selected time approximately equals the reference clock (Fig.2A, step 118); wherein the medical device system is selected from the group consisting of an external system (connect to port 30, Col.1, lines 30-49), a hybrid system, and an implanted system; wherein the first clock is associated with a monitoring equipment (18) that monitors the patient; wherein the second clock is associated with a bedside device that is coupled to a medical implanted device (e.g. Col.1, lines 30-49).

Regarding claims 45, Aoyama et al. teach receiving an indication from the user through the user interface (26) that the reference time approximately equals the selected time (step 118, Fig.2A).

7. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama et al. (USP 5,921,938) in view of Sato et al. (USP 6,869,966).

Regarding claims 6-9, Aoyama et al. fail to teach the medical device system provides monitoring or treatment for a nervous system disorder; wherein the nervous system disorder is selected from the group consisting of a disorder of a central nervous system, a disorder of a peripheral nervous system, a mental health disorder, and a psychiatric disorder, wherein the nervous system disorder is selected from the group consisting of epilepsy, Parkinson's disease, essential

tremor, dystonia, multiple sclerosis (MS), anxiety, a mood disorder, a sleep disorder, obesity, and anorexia, wherein the nervous system disorder is epilepsy.

Sato et al. teach the medical device system provides monitoring or treatment for a nervous system disorder; wherein the nervous system disorder is selected from the group consisting of a disorder of a central nervous system, a disorder of a peripheral nervous system, a mental health disorder, and a psychiatric disorder, wherein the nervous system disorder is selected from the group consisting of epilepsy, Parkinson's disease, essential tremor, dystonia, multiple sclerosis (MS), anxiety, a mood disorder, a sleep disorder, obesity, and anorexia, wherein the nervous system disorder is epilepsy (e.g. Col.72, lines 34-68).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to inform monitoring or treatment for a nervous system disorder as taught by Sato et al. in a system for synchronizing a plurality of clocks in a medical device system of Aoyama et al. for the purpose of providing treatment of various kinds of cardiovascular disorders, nervous system disorders, metabolic diseases, genital or reproductive disorders, gastro-intestinal disorders, respiratory disorders, inflammatory diseases or glaucoma, and the like (Duffine et al., Col.1, lines 6-13).

8. Claims 17-18, 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama et al. (USP 5,921,938) in view of Duffine et al. (USP 5,752,976).

Regarding claims 17-19, 43-44, Aoyama et al. fail to teach determining that the reference time approximatety equals the first selected time by utilizing the Global Positioning System (GPS) clock reference; determining that the reference time approximately equals the first selected time by utilizing the atomic clock reference; receiving a signal from a wireless communication connection.

Duffine et al. teach determining that the reference time approximatety equals the first selected time by utilizing the Global Positioning System (GPS) clock reference (e.g. Col.12, lines 49-66); determining that the reference time approximately equals the first selected time by utilizing the atomic clock reference (e.g. Col.12, lines 49-66), receiving a signal from a wireless communication connection (e.g. Col.7, lines 23-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the Global Positioning System (GPS) clock reference and the atomic clock reference as taught by Duffine et al. in a system for synchronizing a plurality of clocks in a medical device system of Aoyama et al. for the purpose of providing a patient data communication system for world wide patient location and data and re-programming telemetry with a medical device implanted in the patient (Duffine et al., Col.4, lines 35-38).

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama et al. (USP 5,921,938) in view of Kirkpatrick et al. (USP 6,480,743).

Regarding claim 20, Aoyama et al. fail to teach receiving a signal from an Internet connection.

Kirkpatrick et al. teach receiving a signal from an Internet connection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to inform receiving a signal from an Internet connection as taught by Kirkpatrick et al. in a system for synchronizing a plurality of clocks in a medical device system of Aoyama et al. for the purpose of providing a method for treating a neurological disorder with adaptive stimulation generally begins by detecting an electrographic signal of interest (Kirkpatrick et al., Col.6, lines 7-9).

10. Claims 54-55 are rejected under 35 U.S.C. 103(a) as obvious over Deschamp et al. (USP 5,899,931).

Regarding claims 54-55, Deschamp et al. teach method for synchronizing a first clock (42) and a second clock (18) (e.g. Col.6, lines 18-30), the method comprising: (a) receiving a selected time in a programmer (24), the programmer associated with the first clock (42); (b) setting the first clock (42) to the selected time; and providing a control message to the second clock (18) from the programmer (24), the second clock associated with a medical device (implant medical device 10), wherein the providing of the control message (correction the message, Col.6, lines 46-50) synchronizes the time on the first clock and the second clock, wherein (b) and (c) are not performed simultaneously (e.g. Col.6, lines 18-30).

11. Claims 56-57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deschamp et al. (USP 5,899,931) in view of Duffine et al. (USP 5,752,976).

Regarding claims 56-57, 59, Deschamp et al. fail to teach receiving a signal from a Global Positioning System (GPS) reference; receiving a signal from

a control line, the control line coupling the programmer to a second medical device; receiving a signal from a wireless communication connection.

Duffine et al. teach receiving a signal from a Global Positioning System (GPS) reference (e.g. Col.12, lines 49-66); receiving a signal from a control line, the control line coupling the programmer to a second medical device (e.g. Col.6, lines 20-25); receiving a signal from a wireless communication connection (e.g. Col.7, lines 23-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to inform receiving a signal from a Global Positioning System (GPS) reference; receiving a signal from a control line, the control line coupling the programmer to a second medical device, receiving a signal from a wireless communication connection as taught by Duffine et al. in a system for synchronizing a plurality of clocks in a medical device system of Deschamp et al. for the purpose of providing a patient data communication system for world wide patient location and data and re-programming telemetry with a medical device implanted in the patient (Duffine et al., Col.4, lines 35-38).

12. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deschamp et al. (USP 5,899,931) in view of Kirkpatrick et al. (USP 6,480,743).

Regarding claims 58, Deschamp et al. fail to teach receiving a signal from an Internet connection.

Kirkpatrick et al. teach receiving a signal from an Internet connection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to inform receiving a signal from an Internet connection as

taught by Kirkpatrick et al. in a system for synchronizing a plurality of clocks in a medical device system of Deschamp et al. for the purpose of providing a method for treating a neurological disorder with adaptive stimulation generally begins by detecting an electrographic signal of interest (Kirkpatrick et al., Col.6, lines 7-9).

Allowable Subject Matter

13. Claims 5, 10, 22, 24-25, 27, 30, 36, and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 5, none of the prior art of record teaches or suggests the combination of a method for synchronizing a plurality of clock, the plurallty of clocks comprising a first clock and a second clock, the method comprising: (a) disabling a run time mode; (b) receiving a selected time associated with the second clock, the selected time different than a reference time that is associated with the first clock, wherein at least one of the first clock or the second clock is associated with a medical device system; (c) determining when the reference time equals the selected time; (d) setting the second clock to the selected time, in response to (c); and (e) enabling the run time mode, wherein the plurality of clocks comprises a third clock, further comprising the steps of: (f) receiving the selected time that is associated with the third clock; and (e) setting the third clock to the selected time, in response to step (c). It is these limitations as they

are claimed in the combination with other limitations of claim, which have not been found, taught or suggested in the prior art of record, that make these claims allowable over the prior art.

Regarding claim 10, none of the prior art of record teaches or suggests the combination of a method for synchronizing a plurality of clock, the plurallty of clocks comprising a first clock and a second clock, the method comprising: (a) disabling a run time mode; (b) receiving a selected time associated with the second clock, the selected time different than a reference time that is associated with the first clock, wherein at least one of the first clock or the second clock is associated with a medical device system; (c) determining when the reference time equals the selected time; (d) setting the second clock to the selected time, in response to (c); and (e) enabling the run time mode, wherein (b) comprises: (i) sending a command that is associated with the first clock; (ii) determining a delay time between the first clock and the second clcok; and (iii) adjusting the selected time using the delay time. It is these limitations as they are claimed in the combination with other limitations of claim, which have not been found, taught or suggested in the prior art of record, that make these claims allowable over the prior art.

Regarding claim 11, none of the prior art of record teaches or suggests the combination of a method for synchronizing a plurality of clock, the plurallty of clocks comprising a first clock and a second clock, the method comprising: (a) disabling a run time mode; (b) receiving a selected time associated with the second clock, the selected time different than a reference time that is associated

with the first clock, wherein at least one of the first clock or the second clock is associated with a medical device system; (c) determining when the reference time equals the selected time; (d) setting the second clock to the selected time, in response to (c); and (e) enabling the run time mode, wherein (b) comprises: (i) sending a command that is associated with the first clock; (ii) determining a delay time between the first clock and the second clcok; and (iii) storing the delay time. It is these limitations as they are claimed in the combination with other limitations of claim, which have not been found, taught or suggested in the prior art of record, that make these claims allowable over the prior art.

Regarding claim 22, none of the prior art of record teaches or suggests the combination of a method for synchronizing a plurality of clock, the plurallty of clocks comprising a first clock and a second clock, the method comprising: (a) disabling a run time mode; (b) receiving a selected time associated with the second clock, the selected time different than a reference time that is associated with the first clock, wherein at least one of the first clock or the second clock is associated with a medical device system; (c) determining when the reference time equals the selected time; (d) setting the second clock to the selected time, in response to (c); and (e) enabling the run time mode; (f) receiving a current time from the second clock; (g) subtracting the current time from the reference time in order to determine a time difference; and (h) if the time difference is greater than a first predetermined amount, resynchronizing the first and second clocks. It is these limitations as they are claimed in the combination with other limitations of

claim, which have not been found, taught or suggested in the prior art of record, that make these claims allowable over the prior art.

Regarding claim 24, none of the prior art of record teaches or suggests the combination of a method for synchronizing a plurality of clock, the plurallty of clocks comprising a first clock and a second clock, the method comprising: (a) disabling a run time mode; (b) receiving a selected time associated with the second clock, the selected time different than a reference time that is associated with the first clock, wherein at least one of the first clock or the second clock is associated with a medical device system; (c) determining when the reference time equals the selected time; (d) setting the second clock to the selected time, in response to (c); and (e) enabling the run time mode; wherein the first clock and the second clock are located in different time zones. It is these limitations as they are claimed in the combination with other limitations of claim, which have not been found, taught or suggested in the prior art of record, that make these claims allowable over the prior art.

Regarding claim 25, none of the prior art of record teaches or suggests the combination of a method for synchronizing a plurality of clock, the plurallty of clocks comprising a first clock and a second clock, the method comprising: (a) disabling a run time mode; (b) receiving a selected time associated with the second clock, the selected time different than a reference time that is associated with the first clock, wherein at least one of the first clock or the second clock is associated with a medical device system; (c) determining when the reference time equals the selected time; (d) setting the second clock to the selected time, in

response to (c); and (e) enabling the run time mode; wherein (d) comprises (i) adjusting the second clock in accordance with a time transition between standard time and daylight savings time. It is these limitations as they are claimed in the combination with other limitations of claim, which have not been found, taught or suggested in the prior art of record, that make these claims allowable over the prior art.

Regarding claim 60, none of the prior art of record teaches or suggests the combination of a method for synchronizing a first clock, and second clock, the method comprising: a) receiving a selected time in a programmer, the programmer associated with the first clock; b) setting the first clock to the selected time; and C0 providing a control message to the second clock with a medical device, wherein the providing of the control message synchronizes the time on the first clock and the second clock, wherein (a) comprises: (i) receiving a signal from a control line, the control line coupling the programmer to a second medical device; wherein the second medical device includes a third clock and causes the first, second, and third clock to be synchronized . It is these limitations as they are claimed in the combination with other limitations of claim, which have not been found, taught or suggested in the prior art of record, that make these claims allowable over the prior art.

Contact Information

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John H Le whose telephone number is 571-272-2275. The examiner can normally be reached on 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John E Barlow can be reached on 571-272-2269. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John H. Le

Patent Examiner-Group 2863

June 9, 2005

BRYAN BUI
PRIMARY EXAMINER

6/13/05